

# Hidden harmful substances in cosmetic products

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The German Cosmetic Directive (KVO) ensures that the use of cosmetic products is non-hazardous to the health of consumers. As with any other legal regulations there are grey areas that we should know.

**A**s stipulated in the German Cosmetic Directive, the ingredients of cosmetic products are listed on the packages with their INCI denominations (INCI = International Nomenclature Cosmetic Ingredients). The European Commission<sup>1</sup> defines the INCI denominations and lists the terms in the CosIng data base together with their different denotations<sup>2</sup>. Not every substance is suitable for the production of cosmetics. That is why certain annexes of the Cosmetic Directive provide information on substances that are banned (annex II), licensed with restrictions (annex III) or licensed for certain purposes: annex IV (preservatives), annex V (dyes) and annex VI (UV filters). Apart from that, it is established that all other substances not listed in the annexes have to be itemized in the mandatory safety report according to annex I of the German Cosmetic Directive and assessed in terms of their safety for human health. For this report, all relevant toxicological, biological and chemical data of the single substances are collected, examined and then combined as specified in the precise formula. Also potential chemical reactions of the ingredients among each other have to be taken into account.

## Pure substances and complex compounds

As far as discrete substances are concerned, or in other words 100 % pure natural or synthetic single substances, the consumer can trust on the fact that the resulting formulations are state-of-the-art and do not contain any harmful components – it should however be mentioned that the state of the art is continually changing. Chemically discrete substances rather are an exception though. Practically every substance contains traces or admixtures

of other substances. Iron pigments for instance often contain minor amounts of oxides of other heavy metals.

The situation is even more complex with compounds such as extracts, mineral oil components or process-related substances respectively cosmetic additives (emulsifiers, consistency agents etc.). There are also influences not taken into account by the German Cosmetic Directive. Besides the environmental compatibility of formulations, they comprise product modifications caused by packaging and storage, atmospheric impacts after opening the containers and impacts involved with the daily use by consumers. In this context, not only harmless substances come into play but also harmful substances and substances that are banned in the German Cosmetic Directive. They do not show up on the INCI list.

## Banned substances<sup>3</sup>

As already mentioned above, pigments and first and foremost minerals can naturally contain traces of other substances that are not wanted but sometimes cannot be avoided due to technical reasons. Among them are heavy metals such as lead, cadmium, mercury, nickel but also chromium in its carcinogenic oxidation state VI. A typical example is the lead content in natural kaolin that is unwanted and technically unavoidable but non-hazardous to human health. It is not unusual that contents of 10 mg/kg (10 ppm) are found. Lead belongs to the group of banned substances. In such cases when examining, the Governmental Investigations Offices decide in such a way that the manufacturer selects the least contaminated among the available raw materials. Kaolin is an ingredient of makeup preparations and enzyme peeling masks.

A further example worth mentioning is open-cast-mined medicinal clays that do not only enclose minerals but due to their filter effects also contain air pollutants such as dioxins.

<sup>1</sup> 96/335/EC: Commission Decision of 8 May 1996 establishing an inventory and a common nomenclature of ingredients employed in cosmetic products

<sup>2</sup>

[https://ec.europa.eu/growth/sectors/cosmetics/cosing\\_de](https://ec.europa.eu/growth/sectors/cosmetics/cosing_de)

<sup>3</sup> Stand KVO: 30. Januar 2016, (BGBl. I S. 108, 109)

Hence the analytical results have to be closely monitored. Mineral clays (alias healing earths) are used as a base material for (cleansing) masks.

Similar monitoring is required for mineral oils and mineral waxes (paraffins, petrolatum, microcrystalline waxes, ozocerite etc.) since they also contain unwanted aromatic hydrocarbons (MOAH = Mineral Oil Aromatic Hydrocarbons) and polycyclic aromatic hydrocarbons (PAH) besides saturated hydrocarbons (MOSH = Mineral Oil Saturated Hydrocarbons), a fact which depends on the provenance and the efficacy of the refining processes. Various cosmetic products contain mineral oil products for skin re-fattening purposes.

But also CMR substances, or in other words, carcinogenic, mutagenic or teratogenic substances can be present in cosmetic products, even though they are – according to legal interpretation – produced under good manufacturing practice (GMP), not intentionally added but are technically unavoidable and the cosmetic product is safe to human health.<sup>4</sup> As components of INCI ingredients they are not mentioned in the INCI declaration. The situation is different with intentionally added CMR substances where there are no alternatives. The given concentrations have to be safe to human health and the substances have to be mentioned in the INCI declaration. Among them are also substances listed in the annexes III and IV of the German Cosmetic Directive.

Dioxane also belongs to the banned substances, but may be present as a production-related contaminant in polyethylene glycols (PEG) and ethoxylated alcohols. These compounds are used as consistency agents, moisturizing agents and emulsifiers.

The situation with natural products such as herbal extracts, essential and fatty oils is rather confusing since they may contain several hundred single components with most of them originating from the unprocessed plants, others however form during processing. Just to mention some examples:

- Hydroquinone (banned substance) forms through hydrolysis from arbutin-containing extracts.
- Methyl eugenol in essential oils: Depending on the intended use of the cosmetic product, the German Cosmetic Directive tolerates maximum natural contents between 0.0002 (leave-on products) and 0.01% (perfume).

<sup>4</sup> Keck-Wilhelm A, Kratz E, Baumung C, Gutsche B, Schneider B, Mildau G, Verbotene Stoffe in kosmetischen Mitteln, Zeitschrift für Stoffrecht 14 (4), 162-168 (2017)

- Declarable components have to be listed when fragrance contents are higher than 0.001% (leave-on products) respectively 0.01 (rinse-off products).
- 3-MCPD (3-Monochloropropane diol), glycidol (2,3-Epoxy-1-propanol) and its fatty acid esters can form during the refining processes of herbal oils.<sup>5</sup>

Banned substances can also form when substances react with each other, and nitrosamines can serve as an example here since they can develop from secondary amines and amides in the presence of particular preservatives. This applies to N-methylated amino acids such as N-Methyl glycine (Sarcosin) and naturally occurring secondary amines from herbal extracts in the presence of nitrite-supplying preservatives in the preparations such as 5-Brom-5-nitro-1,3-dioxane und 2-Brom-2-nitro-1,3-propandiol, both are licensed up to a content of 0.1%. The German Cosmetic Directive explicitly bans the mentioned mixtures.

Yet, traces of nitrosamines cannot be excluded since secondary amines also react with atmospheric nitrogen oxides as nitrite suppliers, a process which, at the latest, can occur with the application on the skin where the low pH level produced by the dermal microbiome has catalyzing effects.

#### Unwanted substances forming during storage and application

Atmospheric oxygen is also relevant for modifications of skin care components during storage and application – often in combination with radiation and increased temperature. Typical result is the formation of allergenic and irritant oxides and peroxides:

- tea tree oil – ascaridol
- colophony (alias rosin) – oxides of abietic acid
- herbal oils – peroxides of unsaturated acids
- products with essential fatty acids hence should be applied in the evening; if applied by day, sun radiation should be avoided
- polyethylene glycols (PEG) – peroxides

<sup>5</sup> 3-MCPD-, 2-MCPD- Glycidyl-Fettsäureester in Lebensmitteln: EFSA und BfR sehen Gesundheitsrisiko vor allem für jüngere Bevölkerungsgruppen, Mitteilung Nr. 020/2016 des BfR vom 07. Juli 2016

Most frequent active agent in self-tanners is dihydroxyacetone (DHA) – although naturally occurring in the human body, the substance as such or preparations containing it have to be stored at a temperature below 20°C. Otherwise, traces of formaldehyde (banned substance) may form.

On the other hand it should be mentioned that the German Cosmetic Directive seems inconsequent in so far as formaldehyde donors still are licensed as preservatives. In other words, free formaldehyde is not present in these compounds though, but the reaction with microorganisms is identically with that of formaldehyde. Needless to say, this also applies to the reaction with the components of the skin.

The few examples mentioned above prove that it is advisable to fill cosmetic products into light- and air-tight disposable dispensers with double-bottom and store them in the refrigerator at a temperature between 5-10°C just to be on the safe side.

Harmful substances can also dissolve out of inappropriate container material. That should be taken into consideration with plastics recycled in Far East. Suppliers usually provide detailed specifications on observed threshold values for a multitude of pesticides. Particularly W/O emulsions with short-chained esters as well as non-aqueous products can dissolve declared or not declared residues of harmful substances out of the plastics.

Apropos heavy metals: Polyethylene glycols can act as catalysts in the case of nickel release from fashion jewellery and in this way cause nickel allergies during application. Complexing hydroxy acids such as citric acid in combination with low pH levels of preparations have similar effects while strong complexing agents such as EDTA also release Nickel but simultaneously form strong bonds.

### **Persistent substances**

EDTA indeed is disadvantageous in so far as it is a rather persistent substance, thus passes through the sewage treatment plants and dissolves heavy metals in the water bodies. On and within the skin it binds exogenous but also endogenous traces of iron and other physiologically vital heavy metals.

Micro plastics also are persistent and hence potentially harmful substances for the environment. Micro plastics are solid plastic particles smaller than 5 mm. Relevant are rather persistent plastics such as polyethylene (PE) and polypropylene (PP) which both have become a problem in water bodies since they find their way into the food chain via microorganisms, fish and birds where they cause disorders. Polyamides (powders) and the water-

dispersible PEGs and polyacrylates are polymers too which, by definition, also are persistent, however, because of their numerous functional groups they are not inert such as PE and PP but are slowly degraded. That is why they usually are not found in water bodies.

### **Endocrine disruptors**

According to the World Health Organisation (WHO), endocrine disruptors (EDC) are exogenous substances or compounds which modify the hormonal balance and thus affect or damage the human health – to be exact – the single organism, its progeny or a whole population. Providing evidence in the case of cosmetic ingredients is difficult, though. There are numerous publications and studies circulating that either have been partially invalidated or are based on in-vitro- or animal models from where then results were extrapolated to humans. An all-clear-signal has meanwhile been published for parabens.

The preservative triclosan, alias 5-Chloro-2-(2,4-dichlorophenoxy)-phenol, causes fertility disorders and myasthenia and also has carcinogenic potential. Triclosan is only licensed in rinse-off products, which means that the substance should not stay on the skin. When exposed to heat and UV radiation (sun), triclosan is prone to form halogenated dibenzodioxins.

Diethyl phthalate is used as a plasticizer and alcohol denaturant in cosmetics with the alcohol then appearing as Alcohol denat. in the INCI declaration. The German Federal Environmental Agency (UBA) issued a general warning against the use of phthalates since they are suspected of having teratogenic effects, among others. The German Cosmetic Directive already has banned dibutyl phthalate. There is a debate among experts concerning the endocrine activity of the UV filters ethylhexyl methoxycinnamate, butyl methoxydibenzoylmethane, octocrylene, 4-methylbenzylidene camphor and benzophenone since data are based on in-vitro-tests and artificial animal models. The substances mentioned are suspected of contributing to coral death in the Great Barrier Reef in Australia.

### **Further information – data bases**

Detailed and solid information and primary sources on cosmetic ingredients, besides the already mentioned references, can be found in the following:

[https://ec.europa.eu/growth/sectors/cosmetics/cosing\\_de](https://ec.europa.eu/growth/sectors/cosmetics/cosing_de)

[https://ec.europa.eu/health/scientific\\_committees/consumer\\_safety/opinions\\_en](https://ec.europa.eu/health/scientific_committees/consumer_safety/opinions_en)

[http://www.bfr.bund.de/de/gesundheitsliche\\_bewertung\\_von\\_kosmetischen\\_mitteln-242.html](http://www.bfr.bund.de/de/gesundheitsliche_bewertung_von_kosmetischen_mitteln-242.html)  
<https://echa.europa.eu/de/information-on-chemicals>  
<https://www.cir-safety.org/ingredients>  
<http://www.cosmeticsinfo.org>  
<https://toxnet.nlm.nih.gov>  
<http://www.ifraorg.org/en-us/standards>  
<http://www.efsa.europa.eu/de>

<https://www.ewg.org/skindeep>  
[https://pflanzen.fnr.de/industriepflanzen/medizinische\\_pflanzen/pflanzen](https://pflanzen.fnr.de/industriepflanzen/medizinische_pflanzen/pflanzen)  
<https://www.awl.ch/heilpflanzen>

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